EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados, Plaintiff, v. ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION, Defendants.	C.A. No. 05-586 (KAJ)

ANDRX'S RESPONSE TO BIOVAIL'S FIRST SET OF INTERROGATORIES

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure and Local Civil Rules 5.4 and 26.1 of the United States District Court for the District of Delaware, Defendants Andrx Pharmaceuticals LLC and Andrx Corporation (collectively "Andrx"), by its undersigned attorney, hereby respond to plaintiff Biovail Laboratories International SRL's (herein "Biovail") First Set of Interrogatories to Defendant Andrx (Nos. 1 – 11):

a. These responses and objections are served on behalf of Defendants. The information supplied herein is not based solely on the knowledge of the executing individual, but includes the knowledge of the Defendants' agents, representatives and attorneys, unless privileged.

b. Note that the word usage and sentence structure is that of the attorneys and does not purport to be the exact language of the executing party.

GENERAL OBJECTIONS – INCLUDING ANDRX'S OBJECTIONS TO BIOVAIL'S DEFINITIONS AND INSTRUCTIONS.

1. With respect to Andrx's objections, "and" and "or" shall be construed conjunctively or disjunctively to make Andrx's objection(s) inclusive rather than exclusive.

2. Andrx objects to each and every Interrogatory to the extent that it seeks information or documents subject to the attorney-client privilege or attorney work-product immunities. Andrx further objects to each and every Interrogatory to the extent that it seeks the disclosure of opinions, mental impressions, legal conclusions or legal theories of Andrx, Andrx's counselors or representatives or any documents prepared in anticipation of litigation or for trial.

3. Andrx objects to each and every Interrogatory to the extent that it purports to oblige Andrx to perform a legal or other analysis to determine whether a document supports or refutes any claim asserted by Biovail.

4. Andrx objects to Biovail's Interrogatories to the extent that Biovail seeks to require Andrx to provide any information beyond what is available to Andrx at present from a reasonable search of its own files at its principal offices and facilities, and from reasonable inquiry of its present employees, on the grounds that such discovery would be unreasonably cumulative and unduly burdensome.

5. Andrx objects to each and every Interrogatory to the extent that it is intended to impose duties upon Andrx, or seeks information or documents beyond the scope of discovery as set forth in the Federal Rules of Civil Procedure.

6. Andrx objects to each and every Interrogatory to the extent it seeks information or documents that are not in Andrx's possession, custody or control and to the extent such

Interrogatory purports to require Andrx to search for information not within its possession, custody or control.

7. Andrx reserves its right to supplement its responses to Biovail's Interrogatories as information, if any, comes into its possession, custody or control.

8. Andrx objects to each and every Interrogatory to the extent that it is vague, ambiguous or overly broad.

9. Andrx objects to each and every Interrogatory to the extent that it seeks information or documents containing or constituting trade secrets, confidential business or other proprietary information or information protected from disclosure by law, court order or agreement respecting confidentiality or non-disclosure.

10. Andrx objects to each and every Interrogatory to the extent that it calls for responses that were provided to Biovail in *Biovail Corp. Int'l. v. Andrx Pharm. Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000) *aff'd* 239 F.3d 1297 (Fed. Cir. 2001).

11. Andrx objects to each and every Interrogatory to the extent that it seeks information neither relevant to the subject matter of this litigation nor reasonably calculated to lead to the discovery of admissible evidence.

12. Andrx objects to each and every Interrogatory as improper on the grounds and to the extent that compliance would be unduly burdensome. As used herein, "unduly burdensome" means that the Interrogatory requires an unreasonably extensive or expensive search for information and documents that are of little or no value to this lawsuit such that the burden and expense of obtaining the information or documents far outweighs the value of their production.

13. Nothing in these responses shall be construed to waive rights or objections which otherwise might be available to Andrx, nor shall Andrx's answering of any of the Interrogatories

be deemed an admission of relevancy, materiality or admissibility in evidence of the Interrogatory or of the responses thereto.

14. An objection based on attorney-client privilege or the protection afforded by the attorney work-product doctrine shall not be construed as a representation that such information exists or existed. Any such objection indicates only that the Interrogatory is of such a scope as to embrace subject matter protected by the attorney-client or work-product immunity.

15. To the extent that Biovail's Interrogatories seek information from, or the identification of documents from, the internal work-product files or attorneys representing or advising Andrx, Andrx objects generally to the listing of such documents.

16. Since discovery is only beginning in this case, Andrx's responses to Biovail's Interrogatories should not be deemed exhaustive. The following responses reflect Andrx's present knowledge, information and belief and may be subject to change or modification based on Andrx's further discovery, or on facts or circumstances that may come to Andrx's knowledge or attention in the future. Andrx reserves the right to include additional information that is obtained during yet to be conducted discovery or investigation.

17. Andrx objects to Biovail's definition of the term "Andrx's proposed generic Cardizem LA product(s)" as overbroad.

18. Andrx objects to Biovail's definition of the term "document" as overbroad.

19. Andrx objects to Biovail's definition of the term "defendant" as overbroad.

20. Andrx objects to Biovail's definition of the term "diltiazem hydrochloride compositions" as overbroad.

21. Andrx objects to Biovail's definition of the term "defendant's diltiazem hydrochloride composition(s)" as overbroad.

22. Andrx objects to the term "prior art" as defined by Biovail to the extent that it is vague, ambiguous or calls for legal conclusions.

23. Andrx objects to Instructions 1-5 as overbroad and seeking to impose obligations beyond those required by the Federal Rules of Civil Procedure.

24. Andrx also objects to Instruction 5 because it is unintelligible.

25. All responses stated below are provided subject to and without waiving any of the objections stated above to the extent that specific General Objections are cited in response to specific Interrogatories, those specific citations are provided because they are believed to be particularly applicable to the Interrogatory, and shall not be construed as a waiver of any other General Objections applicable to information falling within the scope of the Interrogatory. Similarly, the fact that Andrx chooses not to repeat each of the foregoing General Objections for each specific Interrogatory shall not waive any of the above-stated General Objections. By making the responses herein, Andrx does not concede that the information requested is relevant to this action or is reasonably calculated to lead to the discovery of admissible evidence. Andrx expressly reserves the right to object to further discovery into the subject matter of each and every Interrogatory and the introduction into evidence of any response or portion thereof, and to supplement its responses should further investigation disclose responsive information.

RESPONSES TO BIOVAIL'S INTERROGATORIES

INTERROGATORY NO. 1:

For each claim of the '791 patent that Andrx contends is not infringed by Andrx's proposed Cardizem LA products, describe in detail the factual and legal bases for Andrx's contention.

RESPONSE TO INTERROGATORY NO. 1:

In addition to and without waiving the foregoing General Objections, Andrx objects to this Interrogatory to the extent that it asks for information protected by the attorney-client privilege or work-product immunity. Andrx also objects to this Interrogatory because it calls for legal conclusions. Finally, Andrx objects to this Interrogatory because it is premature.

Subject to the foregoing and the General Objections, Andrx responds as follows:

United States Patent No. 5,529,791 (the "'791 patent") will either (a) not be infringed by the making, using, or selling of Andrx's Diltiazem Hydrochloride Extended-release Tablets in 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, and 420 mg strengths ("the Andrx Proposed Product"); or (b) be invalid and/or unenforceable if the claims are asserted to read on the Andrx Proposed Product.

The '791 patent contains four (4) claims of which claim 1 is the only independent claim. The '791 patent issued on June 25, 1996 from U.S. Patent Application No. 08/311,722, claiming the benefit of U.S. Patent Application No. 08/068,951 filed on May 28, 1993 and U.S. Patent Application No. 07/721,396 filed on June 26, 1991. The '791 patent lists Galephar P.R., Inc., Ltd. as the assignee.

Claim 1 of the '791 patent reads as follows:

> 1. An extended-release galenical composition of one or more pharmaceutically-acceptable salts of Diltiazem which comprises beads containing an effective amount of one or more of said Diltiazem salts as the active ingredient, each bead containing one or more of the Diltiazem salts and an effective amount of a wetting agent in admixture with the one or more Diltiazem salts to maintain the solubility of the Diltiazem in each bead, ensuring that the

> solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions which the composition will meet therein, said beads being coated with a microporous membrane comprising at least a water-soluble or water-dispersible polymer or copolymer, and a water-, acid- and base-insoluble polymer and a pharmaceutically-acceptable adjuvant and wherein the wetting agent is selected from the group consisting of sugars, C_{12}-C_{20} fatty acid esters of sucrose or xylose, glycerides of sucrose, fatty acid esters of polyoxyethylene, ethers of fatty alcohols and polyoxyethylene, esters of sorbitan, esters of polyoxyethylene sorbitan, alcohol-polyglycide esters, glyceride-polyglycides, lecithins and combinations thereof.

In short, this claim, and all the claims depending therefrom, requires a bead that comprises an admixture of a wetting agent and diltiazem.

The Andrx Proposed Product is outside any claim of the '791 patent because it does not include a wetting agent admixed with diltiazem. Specifically, the Andrx Proposed Product includes a drug layer containing active ingredient, diltiazem hydrochloride, with ethylcellulose and polyvinylpyrrolidone ("PVP"). Neither ethylcellulose nor PVP are wetting agents. The Andrx Proposed Product, without admixed diltiazem and a wetting agent, is prepared in five (5) separate and distinct manufacturing steps: (1) preparation of active pellets; (2) preparation of extended-release pellets; (3) preparation of an extended-release blend; (4) preparation of extended-release tablets; and (5) preparation of film coated extended-release tablets. Andrx has already provided plaintiff with a copy of its Manufacturing Flow Chart and the Component and Composition Statement, as presented in ANDA 77-686, in the notice sent from Andrx to Biovail referenced in Biovail's Complaint, ¶ 15 ("Notice"). *See* Notice Exhibit A.

As the Federal Circuit explained in Andrx and Biovail's earlier litigation, the term "admixture," as used in the '791 patent claims, has a specific meaning. The term "admixture" means "two or more items…commingled and interdispersed to obtain a homogeneous product." *Biovail Corp. v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1303 (Fed. Cir. 2001); *Biovail Corp. v. Andrx Pharm., Inc.*, 158 F.Supp.2d 1318, 1325 (S.D. Fla. 2000). Under that construction, the district court held, and the Federal Circuit upheld, that Andrx's earlier proposed product did not infringe the '791 patent.

In *Biovail,* the courts' claim construction derived from the prosecution history both of the '791 patent, and that of its sister, United States Patent No. 5,288,505 (the "'505 patent"). According to the Federal Circuit, "when patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." *Biovail Corp. Int'l. v. Andrx Pharm. Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001). The prosecution history of the '791 patent and that of the '505 patent bear on the construction of the '791 patent's claims.

The Andrx Proposed Product, by layering active drug onto sugar seeds, does not contain an "admixture" of a *wetting agent* with its diltiazem active ingredient. The Andrx Proposed Product layers diltiazem, ethylcellulose, and polyvinylpyrrolidone ("PVP" or "povidone") onto a sugar core. The prosecution history of the '505 patent clearly indicates that PVP and ethylcellulose are not "wetting agents" within the scope of the claims of the '505 patent. All reference to PVP as a wetting agent was removed from the claims and the specification during prosecution of the '505 patent. Further, the inventor of the '505 patent and the attorney prosecuting the '505 patent argued that the layering of diltiazem onto a sugar seed, as taught in a prior art reference, Debregeas et al., was not a homogeneous admixture as required by the claims

of the '505 patent. *See* June 22, 1992 Amendment, April 26, 1993 Amendment After Final Rejection, May 3, 1993 Information Disclosure Statement and April 20, 1993 Declaration Under 37 C.F.R. 1.132. *See also Biovail* 239 F.3d at 1301-02.

Therefore, the Andrx Proposed Product cannot literally infringe any claim of the '791 patent because it does not contain an admixture of diltiazem and a wetting agent. The only ingredients that are in admixture with the diltiazem in the beads of the Andrx Proposed Product are ethylcellulose and povidone. Neither ethylcellulose nor povidone are within the meaning of the term "wetting agents" as defined in the '791 patent.

The doctrine of prosecution history estoppel and prior art estoppel preclude the claims of the '791 patent from being expanded under the doctrine of equivalents to include the Andrx Proposed Product. *Biovail*, 239 F.3d at 1303-04 and *Biovail*, 158 F.Supp.2d at 1327. More specifically, during prosecution of the '791 patent application, a preliminary amendment distinguished the invention of the '791 patent from the prior art. The prior art described diltiazem in admixture with only PVP, and not with the "core" of that composition. The preliminary amendment went on to clarify that the saccharose contained in the central core of the bead cannot act as a wetting agent and that polyvinylpyrrolidone is a binder and plasticizing agent, not a wetting agent.

In view of the distinction of the '791 formulation from the prior art, the Examiner allowed the claims of the '791 patent.

It is clear that the '791 patent claims do not include povidone (PVP) as a wetting agent nor do they include the layering of a diltiazem layer onto an inert sugar seed, which is the Andrx Proposed Product. Further support can be found in the *Biovail* district court opinion wherein the

district court held that the patent owner admitted that ethylcellulose and povidone are not wetting agents within the scope of the '791 patent. *Biovail*, 158 F.Supp.2d at 1325.

In addition to the foregoing, Biovail, Galephar and their related entities are barred from suing Andrx for infringement of the '791 patent under the doctrine of *res judicata*, which bars a subsequent claim when a court of competent jurisdiction entered a final judgment on the merits of the same cause of action in a prior lawsuit between the same parties. The claims of the '791 patent are unambiguously limited to diltiazem beads and not a specific dosage form containing the beads. The beads employed in the Andrx Proposed Product are identical to the composition of the beads employed in its TAZTIA® product. Therefore, the issue of whether the beads in the Andrx Proposed Product infringe the claims of the '791 patent was decided, and a final judgment entered, in the *Biovail* case (239 F .3d 1297). Thus, under the doctrine of *res judicata*, the Andrx Proposed Product cannot infringe any claim of the '791 patent.

Any assertion that the Andrx Proposed Product infringes any of the claims of the '791 patent is also barred by the doctrine of collateral estoppel (issue preclusion).

The U.S. Court of Appeals, 3rd Circuit, has established the following test to determine if collateral estoppel is applicable:

(1) the issue sought to be precluded is the same as that involved in the prior action;

(2) that issue was actually litigated;

(3) it [was] determined by a final and valid judgment; and

(4) the determination was essential to the prior judgment.

All the above criteria are met in the present matter. First, the issue of infringement of the '791 patent by the Andrx Proposed Product is identical to the issues in the prior proceeding between Biovail et al. and Andrx. *Biovail* 239 F.3d 1297 and *Biovail* 158 F.Supp.2d 1318.

Specifically, the prior lawsuit addressed the issue of whether the beads employed in the Andrx Proposed Product contain an admixture of diltiazem and a wetting agent.

Second, this issue was actually litigated in the prior Biovail case. Biovail et al. had a full and fair opportunity to litigate the "admixture" issue in the prior lawsuit. More specifically, Biovail et al. were granted and conducted a full trial and an appeal on the admixture issue. Based upon these facts, Biovail et al. are barred under the doctrine of collateral estoppel from asserting that the beads of the Andrx Proposed Product infringe and claim of the '791 patent.

Third, United States District Court for the Southern District of Florida reached a valid and final decision on this issue. And the Federal Circuit Court of Appeals upheld that decision on appeal. *See Biovail Corp. Int'l. v. Andrx Pharm. Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000) *aff'd* 239 F.3d 1297 (Fed. Cir. 2001)

Fourth, the admixture issue was a critical and necessary part of the judgment in the first lawsuit. *Biovail*, 239 F .3d at 1301 (wherein the court stated "this case turns on whether the admixture limitation in [the claims of the] patent must be 'homogeneous.'")

For the above reasons, Andrx' Proposed Product will not infringe any claims in the '791 patent.

Finally, if the claims of the '791 patent are interpreted to include the Andrx Proposed Product, then the claims are invalid under 35 U.S.C. § 102(b) and/or 103(a) in view of the teachings of EPO 0 320 097 (EPO '097). The EPO '097 was published on June 14, 1989, more than one year before earliest filing date of the '791 and '505 patents (June 26, 1991), and discloses diltiazem beads prepared by applying to a sugar seed an admixture of diltiazem and an organic acid, then coating the diltiazem layer with an insoluble polymer, a water-soluble polymer, and a pharmaceutically acceptable adjuvant. EPO '097 also discloses that the pellets

can be compressed into tablets with excipients such as microcrystalline cellulose or sucrose. Thus, if asserted as encompassing the Andrx Proposed Product, the claims of the '791 patent would read on the prior art, which is prohibited under the U.S. Patent Laws.

INTERROGATORY NO. 2:

For each claim of the '791 patent that Andrx contends is invalid, describe in detail the factual and legal bases for Andrx's contention.

RESPONSE TO INTERROGATORY NO. 2:

In addition to and without waiving the foregoing General Objections, Andrx objects to this Interrogatory to the extent that it asks for information protected by the attorney-client privilege or work-product immunity. Andrx also objects to this Interrogatory because it calls for legal conclusions. Finally, Andrx objects to this Interrogatory because it is premature.

Subject to the foregoing and the General Objections, Andrx hereby incorporates by reference its Response to Interrogatory No. 1.

INTERROGATORY NO. 3:

Identify whether Andrx requested, obtained, and/or conducted any opinions, studies, analyses, reports, tests or investigations, whether written or oral, relating to the validity or infringement (actual or potential) of any claim or claim element of the '791 patent (including but not limited to the claim element of "an effective amount of a wetting agent in admixture with the one or more Diltiazem salts"), or any related patent, either U.S. or foreign. If Andrx's answer is anything other than an unqualified "no," for each such opinion, study, analysis, report, test or investigation, identify: